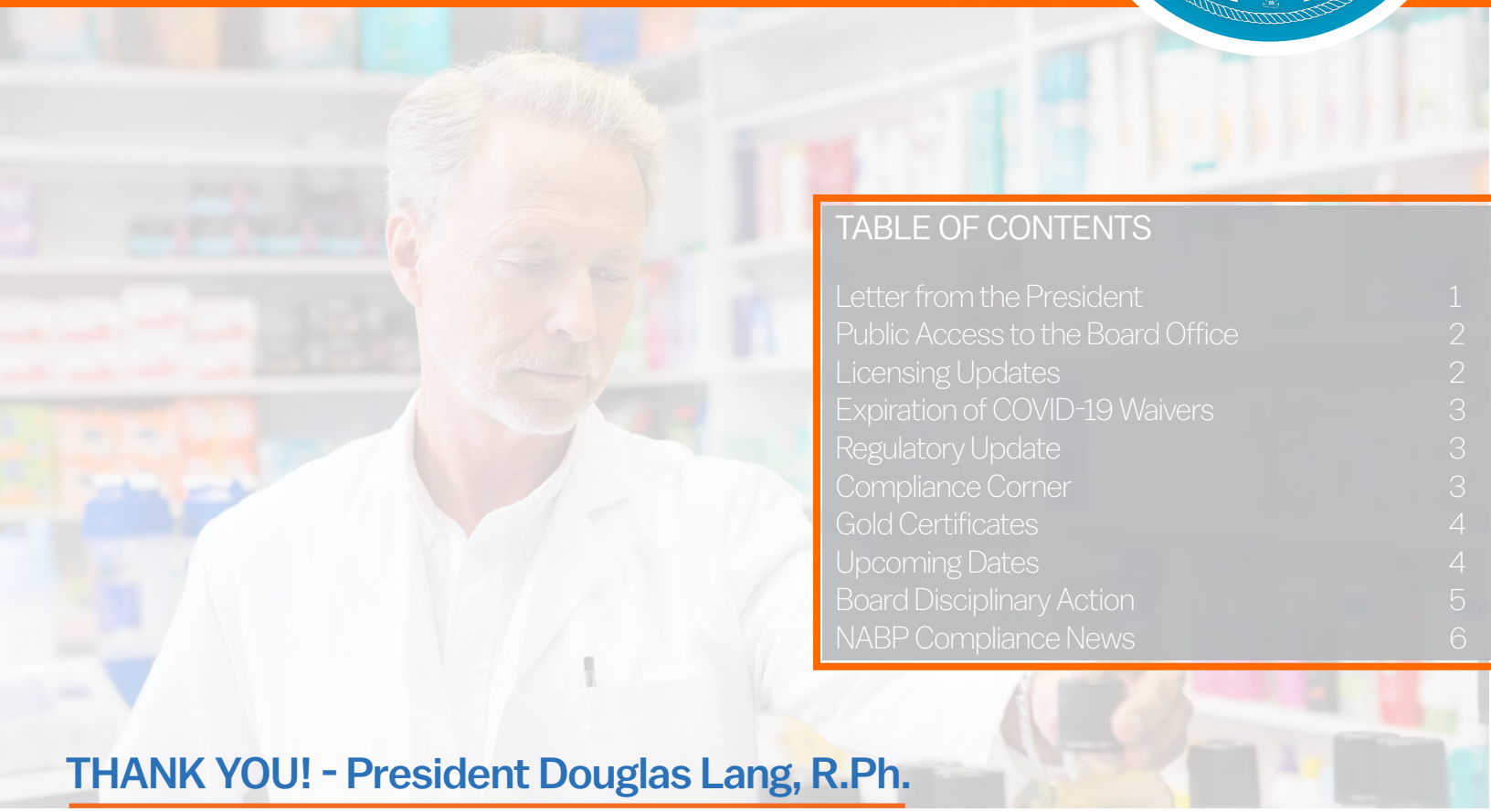
MISSOURI BOARD OF PHARMACY

NEWSLETTER

JUNE 2020



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THANK YOU! - President Douglas Lang, R.Ph.

2020 has already proven to be an unpredictable year! As it has been stated, it is truly an unprecedented time as healthcare practitioners and providers, in serving the ongoing pharmacy needs of the public, no matter the practice setting of pharmacy.

As the President of the Board, the Board extends its appreciation and thanks to all of the Board's licensees and registrants who have risen to the occasion during the COVID-19 pandemic to take care of Missouri patients. Many of you went over and beyond as you worked extra hours, expanded home deliveries, extended pharmacy hours, staffed Missouri's hospitals/clinics and made deliveries of medications and medical supplies to pharmacies and hospitals/clinics. Your efforts were especially remarkable given many of you had to manage staff shortages, as well as respond to state/local shelter at-home orders. In addition, the Board wishes to thank the Board's Executive Director, the Board's staff, the Board's Inspectors team, and its legal counsel for continuing to be focused on the needs of the public and our licensees/registrants needs in meeting their mission of serving Missouri patients. Missouri's pharmacy profession is the best in the nation. Thank you for all you do to keep Missouri patients safe and to continue to deliver pharmacy care and medications to ensure a safe and effective medication outcome in a most challenging time.

Missouri's COVID-19 response is still ongoing. We don't know what the future will look like or how COVID-19 may impact pharmacy going forward. As we all adjust to our "new normal," please continue to monitor the Board's website for additional COVID-19 related news and updates.

PUBLIC ACCESS TO THE BOARD OFFICE:

Beginning June 1, 2020, the Division of Professional Registration and the Board of Pharmacy will be accepting members of the public in its building but with some new rules and safeguards.

- If you are an applicant or licensee and you plan to hand deliver items, you will be required to remain in the lobby area to meet with a Board representative. The Division will limit the number of public visitors in the lobby to three (3) people. Additional visitors will be required to remain in your vehicle or outside of the building until you are able to meet with board staff.
- The Division and its boards kindly ask you to socially distance while visiting the Division office. Please have any documents that require notarization completed prior to your visit, including the notarization.
- If you would like to attend a public meeting, the Board will provide information on how to attend the meeting virtually. Individuals who need to gain entry into the building for the meeting (e.g., a hearing) will be required to maintain social distancing in the building. You may be asked to wait outside if you have a scheduled appointment with the board and asked to answer questions regarding your health and any exposure to COVID-19.

LICENSING UPDATES

The Board office is open and processing applications. A few licensing updates:

- The renewal deadline for Missouri pharmacy technicians has been extended until July 31, 2020, due to COVID-19. All pharmacy technician registrations must be renewed by July 31st. Registrations not renewed by July 31st will be deemed expired and void. No grace period will be granted after July 31st, in light of the extended deadline. Technicians will not be able to work after July 31, 2020, if their registrations have not been renewed.
- Pharmacist renewals will be mailed around August 1st and must be renewed by October 31st. Licensees are encouraged to renew online to prevent delays. To renew, pharmacists must have completed thirty (30) hours of continuing education (CE) between November 1, 2018, and October 31, 2020. You will be asked to attest that your CE is complete when you renew. Do not renew if you have not completed the required thirty (30) hours of CE at the time you submit your paper or online renewal application. CE cannot be completed after your Missouri renewal is submitted.
- The Board will be auditing all pharmacists to verify compliance with the CE requirement using CPE Monitor. The Board was advised last year that certain national CE providers mistakenly listed the wrong CE dates for Missouri licensees. Check CPE monitor to make sure your CE is current and accurate, and falls within the appropriate CE timeframe (11/1/18 – 10/31/20). Note: *CE sponsored by the Missouri Board of Pharmacy is not reported to CPE monitor at this time. Licensees without 30 CE hours registered in CPE monitor during the CE timeframe will be asked to mail proof of Board CE hours to the office. Do not mail in certificates for Missouri Board CE programs at this time; You will be notified if proof of Board CE is required)*
- Address Changes for Licensees/Registrants Seeking To Renew: If you've had a change of address, your address must be updated with the Board before you can renew online. Address changes can be submitted on the Board's website at: https://pr.mo.gov/pharmacists-coa.asp

EXPIRATION OF COVID-19 WAIVERS

Governor Parson recently announced that all COVID-19 statutory/rule waivers approved by the Governor pursuant to Executive Order 20-02 have been extended until **December 30, 2020.** All Board waivers that were set to expire on June 15, 2020 and September 1, 2020, will now be in effect until **December 30, 2020**. A list of approved Board COVID-19 waivers is available on the Board's website. Please e-mail the Board at compliance@pr.mo.gov, if you have any additional questions.

REGULATORY UPDATE

The following rule change became effective on May 30, 2020:

- 20 CSR 2220-2.145 (Minimum Standards for Multi-Med Dispensing): Has been revised to extend the authorized beyond-use date for a multi-med pak from 60-days from the date of preparation to 90-days from the preparation date. The rule has also been revised to allow controlled substances to be included in a med-pak, in compliance with state and federal controlled substance laws/regulations.

Pending Rule Changes:

- 20 CSR 2220-6.200 (Pharmacists Prescribing Nicotine Replacement Therapy Products under § 338.665, RSMo)- Public rule comment ended; Final Order of rulemaking pending review by the Missouri Board of Registration for the Healing Arts)
- 20 CSR 2220-2.710 (Pharmacy Technician and Intern Pharmacist Supervision): Final Order of Rulemaking filed; Final effective date pending
- 20 CSR 2220-2.725 (Remote Data Entry): Final Order of Rulemaking filed; Final effective date pending
- 20 CSR 2220-6.055 (Non-Dispensing Activities): Final Order of Rulemaking filed; Final effective date pending.

COMPLIANCE CORNER

The Board recently reviewed a patient complaint where the patient alleged a pharmacist failed to inform them that their prior medication was discontinued and a new medication prescribed. The patient subsequently took both the new and discontinued medication at the same time, allegedly resulting in medical complications.

Patients may not know when their prescriber changes therapy and discontinues a prior prescription. Pharmacists should use their professional judgment to inform patients in these instances and prevent duplicate therapy. The Board recommends that pharmacists counsel patients when medication is replaced and should no longer be taken. Alternatively, a separate patient leaflet/handout advising the patient of the discontinuance and change in therapy may be appropriate.

Licensee should note that patients may overlook a discontinuation/therapy change that is only listed in the prescription label's directions. This may be especially true for patients established on a medication who may mistakenly assume they already know the correct directions for use and may not closely read the prescription label.

The Board recognizes pharmacists may not always know when a prescription has been discontinued. When known, pharmacists should take appropriate steps to identify duplicate therapy and prevent adverse drug events.

GOLD CERTIFICATES

Congratulations to our newest "gold certificate" pharmacists who will have maintained a Missouri pharmacist license for 50 years as of June 1, 2019:

William McHugh	**William Dumey**
Glen D Newman	

UPCOMING DATES

BOARD MEETING | 3 PM

Pending discussion items:

- 2020 New Legislation
- 2021 Legislative Proposals
- Missouri Drug Utilization Review Requirements
- Quality Assurance/Quality Improvement

WEBINAR | 12 PM

"Lunch with the Chief" Webinar (MO HealthNet Update)

BOARD DISCIPLINARY ACTION

PHARMACIES

- APS Pharmacy, #2012034117, Palm Harbor, FL. Three (3) years probation. Disciplinary action in multiple states for unauthorized dispensing of legend drugs. Section 338.055.2 (8) and (15), RSMo.
- Pharmacare Plus, #2016008986, Houston, TX. Three (3) years probation. Failed to respond to document requests; failed to have pharmacists available for counseling. Section 338.055.2 (5) and (6) RSMo.
- Rx Unlimited, #2015012203, Barnhart, MO. Probation for three (3) years. Operated with an expired license. Section 338.055.2(5), (6), (13), and (15) RSMo.

PHARMACISTS

- Baker, Lisa H., #2007038408, Las Vegas, NV. Public Censure. As Pharmacist-in-Charge failed to provide adequate security for controlled substances, failed to maintain accurate controlled substance records. Section 338.055.2 (5), (6),(13), and (15). RSMo.
- Boelling, Nathan T., #2017034441, Columbia, MO. Public Censure. Dispensed controlled substance prescriptions to himself too soon after previous fills. Section 338.055.2(5), (13), and (15), RSM
- Courtright, Brett M., Kansas City, MO. Five (5) years probation. Pled guilty to Conspiracy to Violate the Food, Drug, and Cosmetic Act in violation of 18 U.S.C. § 371 and 545, and 21 U.S.C. §§331 (c) and 222 (a) (2) and conspiracy to Dispense a Controlled Substance Outside the Scope of Legitimate Medical Practice and Not for a Legitimate Medical Purpose in violation of 21 U.S.C. § § 841 (a)(1) and (b)(1)(C) and § 846. Section 338.065.1 RSMo
- Eldridge, Brandon G., #2009020986, Marine, IL. Five (5) years probation. As staff pharmacist, diverted oxycodone, hydrocodone, hydromorphone, and phentermine for personal use and consumption from the pharmacy without a valid prescription. Section 338.055.2 (1), (5), (13), (15) and (17), RSMo
- Mehrle, Andrew, #2014030498, Springfield, MO. Suspended for three (3) years followed by five (5) years probation. Admitted to being under the influence of alcohol while practicing. Section 338.055.2 (1), (5), and, (13), RSMo.
- Palans, Andrew G., Lake St. Louis, MO. Five (5) years probation. As pharmacist-in-charge, violated previous disciplinary order. Failed to verify prescriptions, failed to list all active ingredients not listed on a compounded prescription, failure to separate expired drugs from active inventory, not keeping schedule II controlled substances in a locked cabinet, 338.055.2(5), (6), (13) and (15) RSMo.
- Palans, Andrew G., Lake St. Louis, MO. Five (5) years probation. As pharmacist-in-charge, violated previous disciplinary order. Failed to verify prescriptions, failed to list all active ingredients not listed on a compounded prescription, failure to separate expired drugs from active inventory, not keeping schedule II controlled substances in a locked cabinet, 338.055.2(5), (6), (13) and (15) RSMo.

DISTRIBUTORS

- Guaranteed Returns. #900731, Holbrrok, NY. Five (5) years probation. Found guilty on multiple Class C felony counts of wire fraud under 18 U.S.C. § 1343 in the United States District Court, Eastern District of Pennsylvania. 338.065.1 RSMo.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY® NATIONAL PHARMACY COMPLIANCE NEWS - JULY 2020

(The following information was provided by the National Association of Boards of Pharmacy and is reprinted with permission of NABP. This information is provided for informational purposes only and does not express or represent the views or opinions of the Missouri Board of Pharmacy.)

FDA RELEASES MOU ON HUMAN DRUG COMPOUNDING REGULATION AND OVERSIGHT

Acknowledging the vital role states play in reducing the risks associated with compounded drugs, Food and Drug Administration (FDA) has made available a Final Standard Memorandum of Understanding (MOU) Addressing Certain Distributions of Compounded Human Drug Products, intended to be entered into between the agency and the states. The release of the MOU is required as part of its submission to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The MOU was developed in close consultation with the National Association of Boards of Pharmacy®(NABP®), as described in the Federal Food, Drug, and Cosmetic Act. The agency also engaged with states, pharmacies, associations, pharmacists, and other stakeholders.

Among the issues addressed in the MOU is the definition of the statutory term "inordinate amounts," which refers to compounded drugs that are distributed interstate. In addition, the MOU includes the risk-based oversight model from the 2018 revised draft MOU. States that sign the document agree to identify pharmacy compounders that distribute inordinate amounts (greater than 50%) of compounded drug products interstate, as well as report certain information to FDA about those compounders. FDA also provided clarity in the MOU on state investigations of complaints associated with compounded drugs distributed out of state. States that enter into the MOU will investigate complaints about drugs compounded at a pharmacy within their state and distributed outside of the state and advise FDA when they receive reports of serious adverse drug experiences or serious product quality issues, like drug contamination.

To help states to better investigate these issues, FDA has also announced an agreement with NABP to make an information sharing network available to the states. Through this network, states will be able to obtain infor- mation from pharmacies in their states and transmit that information to FDA.

"We anticipate the final MOU, once signed, will help to facilitate increased collaboration between the FDA and the states that sign it," said Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, in an FDA Voices article. "Working together, we can help promote quality compounding practices and better address emerging public health concerns that may affect patients."

FDA CLARIFIES COMPOUNDING RULES, OFFERS FLEXIBILITY TO HELP EASE DRUG SHORTAGES DURING COVID-19 PANDEMIC

FDA noted it will use discretion in enforcing certain standards related to 503A and 503B compounding in an effort to ease drug shortages during the coronavirus disease 2019 (COVID-19) pandemic. During an American Pharmacists Association (APhA) webinar on April 30, 2020, the agency clarified it will "look to 503B compounders to grapple with drug shortages" and "turn to 503A compounders to fill in the gaps."

In addition, the agency clarified that medications on the FDA drug shortage list are effectively considered "not commercially available," which frees 503A and 503B compounding facilities from limits on compounding drugs that are "essentially a copy" of a product already available on the market. FDA also does not intend to take action if a 503A facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

In April 2020, FDA issued a temporary guidance that granted flexibility for pharmacists to compound certain necessary medications under 503A for nonspecific patients hospitalized due to COVID-19. In addition, a temporary guidance was issued that granted enforcement flexibility for 503B outsourcing compounding facilities for drugs in shortage for patients hospitalized during the COVID-19 public health emergency. The guidance documents stipulate the conditions compounders must meet and are available at https://www.fda.gov/media/137125/download.

More information on these compounding rule clarifications is available in a May 5, 2020 press release on the APhA website.

CMS ALLOWS PHARMACIES TO TEMPORARILY ENROLL AS CLINICAL DIAGNOSTIC LABORATORIES FOR COVID-19 TESTING

Centers for Medicare & Medicaid Services (CMS) has released a document detailing a process that allows pharmacies to temporarily enroll as independent clinical diagnostic laboratories. This process will allow those facilities to seek Medicare reimbursement for COVID-19 tests, making it easier for them to provide that service during the pandemic.

"Up until this point in time, most pharmacies could only offer this as a cash service because they were not considered providers through CMS, and really a lot of the third-party payers really didn't have an interest in a fee-for-service type model," said Michael E. Klepser, PharmD, FCCP, pharmacy professor at Ferris State University, in an interview with Bloomberg Law. "The fact that CMS is saying we're now authorizing or allowing pharmacists to get reimbursed for these is a great door opening at the federal level and that's a huge, huge thing."

Chain pharmacies such as CVS, Walgreens, and Rite Aid are offering drive-through testing at many pharmacies throughout the country.

FDA ISSUES UPDATED GUIDANCE FOR COMPOUNDING PHARMACIES EXPERIENCING PPE SHORTAGES

FDA has issued an update for its guidance to pharmacy compounders that may experience shortages of personal protective equipment (PPE) during the COVID-19 pandemic. As compounders typically utilize PPE when performing sterile compounding, the updated guidance clarifies that the drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom. This policy has been adopted to ensure patients continue to have access to medicines they need during the pandemic, and to reduce the risks of compounding when standard PPE is not available.

In addition to FDA guidance, United States Pharmaco- peial Convention has previously issued an informational document for compounders regarding garb and PPE short- ages during the pandemic. The document includes recom- mendations for conserving garb and PPE and what steps might be considered in the case of shortages of garb and PPE used for both sterile and nonsterile compounding.

The updated guidance can be accessed through FDA's website by visiting www.fda.gov/media/136841/ download.

HHS EXPANDS TELEHEALTH ACCESS IN RESPONSE TO COVID-19

In an effort to prevent and respond to the COVID-19 pandemic, the US Department of Health and Human Services (HHS) has awarded $20 million to increase telehealth access and infrastructure for health care providers and families. The funds, which are awarded through the Health Resources and Services Administration (HRSA), will increase capability; capacity and access to telehealth and distant care services for providers, pregnant women, children, adolescents, and families; and assist telehealth providers with cross-state licensure. "This new funding will help expand telehealth

infrastructure that is already being used during the pandemic to provide essential care, especially to the most vulnerable, including pregnant women and children with special health care needs," said HHS Secretary Alex Azar in a press release. "This funding will also help clinicians use telehealth nationally by streamlining the process to obtain multi-state licensure."

HRSA's Maternal and Child Health Bureau awarded a total of $15 million to four recipients; each award sup- ports a key area in maternal and child health, including pediatric care, maternal health care, state public health systems, and family engagement for children with special health care needs. HRSA's Federal Office of Rural Health Policy awarded a total of $5 million to two recipients through the Licensure Portability Grant Program, which will assist telehealth clinicians nationally on licensure and credentialing to meet emerging needs related to COVID-19.

CRIMINALS FOUND POSING AS CDC REPRESENTATIVES TO STEAL MONEY AND INFORMATION

Centers for Disease Control and Prevention (CDC) is warning the general public of a new type of phone and phishing scam by criminals posing as CDC representatives, often requesting donations. According to CDC, most of these fraudulent activities are being conducted by phone, utilizing software to "spoof" phone calls to make them appear as if they are coming from phone numbers that may look familiar. CDC advises consumers to avoid answering calls from numbers they do not recognize, and to avoid sharing personal information over the phone. In addition, CDC notes that no federal agency will request donations from the general public. Suspicious phone calls may be reported to the Federal Communications Commission.

More information on the scams is available on the CDC website at https://www.cdc.gov/media/phishing.html.